UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,728	12/28/2000	Akihiro Umezawa	766.43	6784

5514 7590 08/07/2002

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER
SHUKLA, RAM R

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/07/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/749,728	Applicant(s) UMEZAWA ET AL.	
	Examiner Ram Shukla	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-91* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

DETAILED ACTION

1. Claims 1-91 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-46 and 76-77, drawn to a multipotent stem cell isolated from a living tissue or umbilical cord and a method of regenerating heart damaged by a heart disease, classified in class 424, subclass 93.1.

II. Claims 47-60, drawn to a method of differentiating a multipotent stem cell into a cardiac cell by treating the stem cell with a DNA-methylating agent, classified in class 435, subclass 375.

III. Claims 61-63, drawn to a method of differentiating a multipotent stem cell into an adipocyte by treating the stem cell with an activator of a nuclear receptor, classified in class 435, subclass 375.

IV. Claims 64-66, drawn to an undefined myocardium forming agent, wherein the agent is a chromosomal DNA methylating agent, classified in class 514, subclass 1.

V. Claims 67-75, drawn to myocardium forming agent wherein the agent is a protein expressed in a fetus, classified in class 530, subclass 350.

VI. Claims 78 and 79, drawn to a method for transfecting a transgene to a myocardium by providing a stem cell, classified in class 424, subclass 93.1.

VII. Claim 80, drawn to a method for producing an antibody that recognizes a specific cell, classified in class 530, subclass 326.

VIII. Claim 81, drawn to a method of purifying a cell using an antibody, classified in class 435, subclass 343.

IX. Claim 82, drawn to a method of isolating a surface antigen specific for a stem cell, classified in class 435, subclass 7.8.

X. Claims 83 and 84, drawn to a method of screening for a factor that induces a stem cell to proliferate and differentiate into a cardiomyocyte, classified in class 435, subclass 4.

XI. Claims 85-89, drawn to a method for immortalizing a cell by expressing a telomerase in the cell and a therapeutic composition the immortalized cell, classified in class 435, subclass 455.

XII. Claims 90 and 91, drawn to a culture supernatant that induces the differentiation of a cell to cardiomyocyte, classified in class 514, subclass 1.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: a cardiomyocytes, an adipocyte, a skeletal muscle cell, an osteoblast, a nervous cell, a hepatic cell and a vascular endothelial cell. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 5 and 6 are generic.

This application contains claims directed to the following patentably distinct species of the claimed invention: it is noted that claims 15-18 recite over 13 patentably distinct species of cell markers. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species of the claimed invention: it is noted that claim 24 recites 12 patentably distinct species of mammals. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

This application contains claims directed to the following patentably distinct species of the claimed invention: it is noted that claims 30-39, 53-60, 68-75 recite a cytokine, an adhesion molecule, a vitamin, a transcription factor and an extracellular matrix components, all of which are patentably distinct. It is noted that dependent claims recite several patentably distinct species of all these species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for claims 30, 53, and 68 and one subspecies of the elected species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions of the groups I, II, III, and VI -XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the invention of group I is drawn to a cell, whereas the inventions of the groups II, III and VI-XII are drawn to various methods that have distinct steps and the methods steps are not co-extensive,

although all the methods use the cell of group I. For example, the method of screening for a factor for cardiomyocyte differentiation would be different from a method of screening for a factor for adipocyte differentiation, since the step of monitoring cell differentiation would be different and distinct for a cardiomyocyte and an adipocyte. The criteria used in monitoring the adipocyte differentiation can not be used in evaluating cardiomyocyte differentiating. Accordingly, the methods of groups II, III and VI-XII are patentably distinct each from the other and they would require a separate and non-coextensive search in the patent and non-patent literature.

5. Inventions of the groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different compositions that have different physical and chemical properties. For example, the invention of group V is drawn to a protein whereas the invention of group IV is drawn to a non-protein chemical. Accordingly, the compositions of groups IV and V are patentably distinct each from the other and they would require a separate and non-coextensive search in the patent and non-patent literature.

6. The methods of groups II, III, VI-XII are patentably distinct each from the inventions of groups I, IV and V because these methods can not be used to make these compositions. While the compositions may be used to perform a certain method, they would have multiple uses as discussed above.

7. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to § 1.121(c). For instructions, Applicants are referred to http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.

RAM R. SHUKLA, PH.D
PATENT EXAMINER